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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	37697-0033	8881

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EXAMINER

BERMAN, SUSAN W

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/764,445	Applicant(s) MERRILL ET AL.	
	Examiner Susan W. Berman	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04-28-2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-130 and 143-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-130 and 143-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Withdrawal of Finality of Office Action

The finality of the rejection of the Office action mailed 07/06/2005 is withdrawn in response to applicant's telephonic request for reconsideration of the rejection of claims under 35 USC 102(a) over Saum et al (6,017,975).

None of the instant claims is clearly drawn to a method comprising irradiation of polyethylene in the melted state (MIR) as disclosed in SN 08/600,744 (US 5,879,400) having a filing date of 02/13/1996. Claims 147-149 encompass the "MIR" method disclosed in '744 and the irradiation and subsequent melting method ("IR-SM") disclosed in SN '313. Thus, claims 147-149 wherein the melting step precedes the irradiation step has an effective filing date of 02/13/1996 with respect to prior art disclosures. However, claims 147-149 wherein the irradiation step precedes the melting step has an effective filing date of 11/02/1996 with respect to prior art disclosures. The instant claims are considered to be supported by the disclosure of SN 08/726,313. Therefore, the earliest effective filing date of the instant claims is considered to be the 10/02/1996 filing date of SN 08/726,313.

The earliest filing date of Saum et al (6,017,975) is the 10/02/1996 filing date of provisional application 60/027,354. Thus, Saum et al '975, having the same effective filing date as the instant claims, is not considered to be a prior art disclosure of the instantly claimed invention under 35 USC 102(a) or under 35 USC 102(e). Applicant argues, in the Remarks filed 04/28/2005, that the earliest 102(a) date of Saum et al '975 is January 25, 2000. This argument is not persuasive because the effective filing date of Saum et al '975 is 10/02/1996 shows that the invention disclosed therein was "known...by others in this country" as set forth in 35 USC 102(a). However, Saum et al '975 is not prior art under 35 USC 102(a) because the effective filing date is not "before the invention thereof by applicant for patent", as set forth in 35 USC 102(a). Applicant's effective filing date with respect to the instant claims is also 10/02/1996.

Response to Arguments

Applicant's arguments filed 04/28/2005 have been fully considered but they are not persuasive.

With respect to applicant's arguments that the instant claims find support in the disclosure of US 5,879,400 (SN 08/600,744 filed 02/13/1996): Claims 147-149 are the only instant claims that are supported by the disclosure of SN '744. Claims 147-149 wherein the "irradiating and melting" steps are performed by melting UHMWPE and subsequently irradiating the melted UHMWPE are entitled to a n effective filing date of 02/13/1996. Claim 128 is not supported because SN '744 does not disclose the swell ratio or degree of oxidation and there is no evidence of record that the methods steps as set forth in claim 147 provide such properties.

US '400 discloses a method (MIR) comprising heating UHMWPE above its melting temperature for a time sufficient to allow the UHMWPE chains to take up an entangled state followed by irradiating g to crosslink and trap the polymer chains in the entangled state. US '400 discloses melting followed by irradiation and varying the dose to control the degree of crosslinking and crystallinity. US '400 does not mention irradiation before melting, heating at a temperature at or above about 150°C for a time sufficient to recombine all the free radicals. See column 2, lines 29-52. Although it is agreed that temperatures above 150°C are broadly disclosed in US '400, there is no recognition of the significance of 150°C in the heating step disclosed. Applicant may not rely upon a "natural consequence of irradiation" that was not mentioned in the disclosure to support claim language setting forth irradiation to form free radicals or heating to recombine free radicals. The disclosure in column 11, lines 22-27 supports the claim language "irradiating ...to form free radicals" however, there is no disclosure that heating cause the free radicals to recombine. Applicant discloses that heating UHMWPE before irradiation in order to allow the polymer chains to take up an entangled state. Applicant discloses that irradiation of melted UHMWPE provides control of crosslinking and crystallinity. US '400 does not disclose the swell ratio or degree of oxidation recitations set forth in instant claims 128-129. See the swell ratios reported in Tables 1, 2 and 6 and the

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discussion of oxidation in column 11, lines 9-14. Applicant is advised to employ the language set forth in the disclosure to provide enablement for the instant claims.

With respect to applicant's arguments that the instant claims find support in the disclosure of SN 08/726,313, filed 10-02-1996: It is agreed that the claims are supported by the disclosure of SN '313 and are entitled to an effective filing date of 10/02/1996. The step of heating to a temperature above about 150° C to recombine free radicals and crosslink the UMWPE is taught on page 9, lines 15-26 and page 14, lines 3-9. The swell ratio and degree of oxidation recitations set forth in claim 128 are taught in Tables 8, 14 and 17.

In summary, applicant is entitled to an effective filing date of 10/02/1996 for instant claims 124-130 and 143-149. These claims set forth methods comprising irradiating an UHMWPE fabricated article and subsequently heating the irradiated UHMWPE article to a temperature above the melting point and the products produced by the recited method steps, as disclosed in SN '313. Claims 147-149 wherein the "irradiating and melting" steps are performed by melting UHMWPE and subsequently irradiating the melted UHMWPE, as disclosed in SN '744, are entitled to an effective filing date of 02/13/1996.

Applicant's arguments with respect to claims 124-130 and 143-146 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The method claims 124, 125, 130, 143 and 147 do not clearly set forth that the fabricated article in the step of heating the fabricated article is the irradiated fabricated article containing

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free radicals formed in the irradiation step. With respect to claims 128-129, the claims recite crosslinked UHMWPE made by the process according to claim 147, however, the process of claim 147 is a process for formation of a medical implant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of 07/09/1996). Applicant's effective filing date for a process comprising irradiation followed by melting the irradiated UHMWPE is 10/02/1996 (filing date of SN 08/726313). Shen et al disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing. See column 4, lines 8-18 and 46-51, column 5, lines 29-52, column 7, lines 20-31, column 7, line 53, to column 8, line 9, column 8, lines 34-64, Example 1 and Figures 4 and 5. Since the process steps set forth in the instant claims are disclosed by Shen et al, the products resulting therefrom would be expected to have the same properties as the medical implants set forth in instant claims 126-129. With respect to claim 147, Shen et al disclose the embodiment of the claimed process wherein an irradiated UHMWPE is melted but do not anticipate the embodiment wherein a melted UHMWPE is irradiated in the melt.

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Claims 126-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of 05/06/1996). Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. See column 3, line 16, to column 5, line 13. With respect to claim 126 and 127, the products disclosed by Hyon et al would be expected to have the same properties as the instantly claimed products. The reason is that Hyon et al disclose the process steps set forth in claims 124 and 125 except for sterilizing the implant and the properties of the product would be expected to be determined by the irradiation and compression-deformation melting steps.

Claims 126-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Salovey et al (6,281,264, having an effective filing date of 01/20/1995). Salovey et al teach a method for crosslinking UHMWPE for forming in vivo implants. The method comprises irradiation crosslinking of a molten polymer. See column 3, lines 50-59, column 4, line 42, to column 5, line 66, column 11, line 38, to column 12, line 11, column 13, lines 44-54. Salovey et al report the effects of the disclosed method on % crystallinity. With respect to claim 126 and 127, the products disclosed by Salovey et al would be expected to have the same properties as the instantly claimed products. The reason is that the process steps disclosed by Salovey et al and set forth in claims 124 and 125 differ only by the order of irradiation and melting and the properties of the product obtained would be expected to be the same in the absence of evidence of differences in properties obtained resulting from irradiating before melting versus melting before irradiation.

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Claims 126-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby et al (5,824,411). Shalaby et al disclose a method that comprises melting an UHMWPE "construct polymer-fiber" and irradiating the resulting composite with high energy radiation to sterilize and crosslink composites of the UHMWPE. See column 2, lines 11-27, column 3, lines 9-18, column 5, line 32, to column 6, line 10, and Examples 1 and 5. Claims 147-149 encompass processes comprising irradiation before heating and processes comprising heating before irradiation. The process steps set forth in claims 147-149 wherein heating to melt occurs before irradiation are taught in the reference. With respect to product claims 128-129, the products disclosed by Shalaby et al would be expected to have the properties recited in the instant claims because the process disclosed by Shalaby et al corresponds to the process set forth in claim 147. With respect to claims 126-127, the products disclosed by Shalaby et al would be expected to correspond to the products set forth because the products are formed by a combination of irradiation and melting. There is no evidence of record that the order of irradiation and melting steps is critical to producing a significantly different product.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of

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compending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129 and 135-137 of compending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-127 of compending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 114 and 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '089 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124,125,129,130,132-134,136, 138, and 145-152 of copending Application No. 10/197263. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

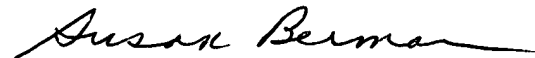
Sun et al (5,414,049) is cited as art of interest. Sun et al disclose a process for providing an implant from UHMWPE. The process steps include melting and forming a polymeric resin into an UHMWPE raw material, such as a rod or bar stock, irradiating a packaged implant at a sterilizing dose of about 2.5 Mrad that causes free radicals to form, and heat treating at temperatures between room temperature and the melting point of the polymer to crosslink the free radicals (column 4, lines 1-44). The irradiating and heating steps are carried out in an oxidant free atmosphere. Sun et al teach melting UHMWPE to form a fabricated article but do not teach melting the fabricated article after forming or after irradiation.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
9/8/05


Susan W Berman
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